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Norman H. Stepno, Esq.
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P.O. Box 1404
Alexandria VA 22313-1404

Re: Patent Term Extension Application for U.S. Patent No. 4,996,335

Dear Mr. Stepno:

A certificate under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 4,996,335 for a period of 1,473 days.

While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). The communication to FDA should include sending a copy of the certificate of extension to New Drug Application and another copy of the certificate of extension to Mary Ann Holovac, who will update the Orange Book. Mary Ann's address is

CDER OIT DDMS
NLRC 235 (HFD-090)
5516 Nicholson Lane
Kensington, MD 20895

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.


Karin Tyson
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: David T. Read Re: LOTELEX™ and ALREX™
Acting Director Regulatory Policy Staff, CDER FDA Docket No. 98E-0789
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE EXTENDING PATENT TERM
UNDER 35 U.S.C. § 156

PATENT NO. : 4,996,335
ISSUED : February 26, 1991
INVENTOR : Nicholas S. Bodor
PATENT OWNER : Nicholas S. Bodor
PRODUCT : LOTEMAX™ and ALREX™ (loteprednol etabonate)

This is to certify that an application under 35 U.S.C. § 156 has been filed in the U.S. Patent and Trademark Office, requesting extension of the term of U.S. Patent No. 4,996,335 based upon the regulatory review of the product loteprednol etabonate (LOTEMAX™ and ALREX™) by the Food and Drug Administration. Since it appears that the requirements of the law have been met, this certificate extends the term of the patent for the period of

1,473 days

from February 26, 2008, the original expiration date of the patent, subject to the provisions of 35 U.S.C. § 41(b), with all rights pertaining thereto as provided by 35 U.S.C. § 156(b).



I have caused the seal of the U.S. Patent and Trademark Office to be affixed this 12th day of September 2000.

A handwritten signature in black ink, appearing to read "Q. Todd Dickinson".

Q. Todd Dickinson

Under Secretary of Commerce for Intellectual Property
and Director of the United States Patent and
Trademark Office